§ 792.105 Test, control, and reference substance characterization.

(a) The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or reference substance shall be determined for each batch and shall be documented before its use in a study. Methods of synthesis, fabrication, or derivation of the test, control, or reference substance shall be documented by the sponsor or the testing facility, and such location of documentation shall be specified.

(b) When relevant to the conduct of the study the solubility of each test, control, or reference substance shall be determined by the testing facility or the sponsor before the experimental start date. The stability of the test, control or reference substance shall be determined before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(c) Each storage container for a test, control, or reference substance shall be labeled by name, chemical abstracts service number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test, control, or reference substance. Storage containers shall be assigned to a particular test substance for the duration of the study.

(d) For studies of more than 4 weeks experimental duration, reserve samples from each batch of test, control, and
§ 792.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information:

(1) A descriptive title and statement of the purpose of the study.
(2) Identification of the test, control, and reference substance by name, chemical abstracts service (CAS) number or code number.
(3) The name and address of the sponsor and the name and address of the testing facility at which the study is being conducted.
(4) The proposed experimental start and termination dates.
(5) Justification for selection of the test system.
(6) Where applicable, the number, body weight, sex, source of supply, species, strain, substrain, and age of the test system.
(7) The procedure for identification of the test system.
(8) A description of the experimental design, including methods for the control of bias.
(9) Where applicable, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or reference substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.
(10) The route of administration and the reason for its choice.
(11) Each dosage level, expressed in milligrams per kilogram of body or